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EXAMINER	
CHNG, JOY P	
ART UNIT	PAPER NUMBER
4114	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,117	PONQUINETTE ET AL.	
	Examiner	Art Unit	
	JOY CHNG	4114	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/11/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 02/11/2004.

2. Claims 1-17 are currently pending and have been examined.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 78, 81 and 83.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "S6" has been used to designate both "Is Wearer Conscious?" and "Alert Medical Authorities".

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "S7" has been used to designate both "Confirm Illness" and "Is Wearer Conscious?".

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections – 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13-17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. As per claim 13, a reference is made to "unequivocally". The limitation "unequivocally" is not defined by the claim, the specification does not provide an appropriate definition, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

All claims dependent thereon, namely claims 14-17, fail to remedy these deficiencies, and are therefore rejected for at least the same rationale above, and incorporated herein.

9. As per claim 17, a reference is made to "intrinsic". The limitation "intrinsic" is not defined by the claim, the specification does not provide an appropriate definition, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

10. The Examiner finds that because particular claims are rejected as being indefinite under 35 U.S.C. 112 second paragraph, it is impossible to properly construe claim scope at this time. However, in accordance with MPEP 2173.06 and the USPTO's policy of trying to advance prosecution by providing art rejections even though these claims are indefinite, the claims are construed and the art is applied as much as practically possible.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 13-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

13. Claim 13 is directed to a process. However, the recited steps of the process are held to be non-statutory subject matter because the recited steps of the process are (1) not tied to another statutory class (such as a particular apparatus) or (2) not transforming the underlying subject matter (such as an article or materials) to a different state or thing.

All claims dependent thereon, namely claims 14-17, fail to remedy these deficiencies, and are therefore rejected for at least the same rationale above, and incorporated herein.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 1-2 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,579,231,B1 to Phipps in view of U.S. Patent 6,665,385 B2 to Rogers et al. and further in view of US Patent 6,539,250 B1 to Bettinger.

Examiner's Note: The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Claim 1:

Phipps discloses the following limitations:

- *a microprocessor* (reads on "processor") *within the central monitoring unit* (reads on "medical monitoring system") *for storing physiological data of a plurality of wearers and for comparing* (reads on "evaluation") *collected real time physiological data with stored base-line physiological data to determine the existence of a medical condition* (reads on "adverse health conditions") *of a wearer* (see at least Col.1, lines 9-13; Claim 27, lines 1-2; Claim 29);

- *a display screen connected to said central monitoring unit for displaying information from a selected remote* (reads on "portable") *monitoring unit* (see at least Col. 3, lines 8-14);

- *a microprocessor* (*reads* on "processor") *located within each remote monitoring unit for comparing* (reads on "evaluate") *collected real time physiological data with stored base-line physiological data to determine the existence of a medical condition* (reads on "adverse health conditions") *of a wearer (*see at least Col.1, lines 9-13; Claim 32, lines 1-7)*;*

- *a memory within each remote monitoring unit including instructions for collecting and storing said real time and base-line physiological data relating to a health condition of a wearer* (see at least Claim 32, lines 3-7; Col. 3, lines 9-12 -)*;*

- *a display connected to said microprocessor located within each remote monitoring unit for displaying instructions for use of the remote monitoring unit* (see at least Col.5, lines 24-26, 30-35)*;*

- *at least one sensor located within each remote monitoring unit and connected to said microprocessor for periodically sampling* (reads on "generating") *physiological data of a wearer* (see at least Claim 1, lines 1-4)*;*

- *a communication device* (reads on "*transmitter*") *located within each remote monitoring unit that transmits collected physiological data from the remote monitoring unit to the central monitoring unit* (reads on "reporting system")(see at least Claim 1, lines 7-9 - P).

Phipps does not disclose the following limitation, but Rogers, as shown does:

- *the central monitoring unit that includes a transceiver for communicating with the remote* (reads on "portable") *monitoring unit* (see at least Fig. 1, Ele. 30, 32; Col.1, lines 26-29)*;*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps with the transceiver of the central monitoring unit of Rogers because it "…supports communication with the portable-monitoring-unit transceiver system" (Rogers, see at least Col.2, lines 27-29).

Phipps and Rogers do not specifically disclose the following limitation, but, Bettinger as shown does:

- *at least one medication storage compartment* (reads on "carrier unit") *located within each remote monitoring unit for storing a medication* (reads on "beneficial fluid") *to be administered in response to a detected medical condition* (reads on "appropriate basis")(see at least Col. 2, lines 15-21; Col. 4, lines 37-39);

- *an transdermal or injection device located within each remote monitoring unit and connected to said at least one medication storage* (reads on "carrier unit") *for delivery of said medication* (reads on "beneficial fluid") *to the wearer when the medical condition is detected* (reads on "appropriate basis")(see at least Col. 2, lines 15-21, 46-50; Col. 4, lines 37-39);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps and the transceiver of the central monitoring unit of Rogers with transdermal device of Bettinger because it provides "...for instantaneous control of the variation in dispensing rate of medication due to the program and/or the sensors" (Bettinger, see at least Col.4, lines 48-51).

Claim 2:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps further discloses the following limitations:

- *a global positioning system receiver that detects a location of the remote monitoring unit, such that said location of the remote monitoring unit may be relayed to the central monitoring unit* (reads on "CRS")(see at least Col. 2, lines 54-57; Col. 8, lines 4-7).

Claim 10:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps further discloses the following limitations:

- *wherein said remote monitoring unit* (reads on "monitoring device") *comprises a speaker* (reads on "beeper") *that alerts nearby individuals to a medical condition of a wearer when the wearer is unconscious* (reads on "subject's vital signs stop")(see at least Fig. 3, Ele. 64; Col. 2, lines 45-49).

Claim 11:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps further discloses the following limitations:

- *a re-transmitter unit* (reads on "transmitter") *that relays information and data between the remote monitoring unit and the central monitoring unit* (reads on "reporting system")(see at least Claim 32, lines 8-10).

17. Claims 3-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,579,231,B1 to Phipps in view of U.S. Patent 6,665,385 B2 to Rogers et al. in view of US Patent 6,539,250 B1 to Bettinger and further in view of U.S. Patent 7,122,005 to Shusterman.

Claim 3:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps, Rogers and Bettinger do not specifically disclose the following limitations, but Shusterman, as shown does:

- *wherein said communications device includes a speaker and microphone for providing audio communications between the wearer and an operator located at the central monitoring unit* (reads on "central station")(see at least Col. 11, lines 15-23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers and the transdermal device of Bettinger with the audio communication of Shusterman because it "...the patient is free to move away from the patient monitoring unit without losing contact with central station" (Shusterman, see at least Col. 11, lines 25-27).

Claim 4:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps, Rogers and Bettinger do not specifically disclose the following limitations, but Shusterman, as shown does:

- *wherein said communications device includes a speaker, microphone and camera* (reads on "visual communication device") *for providing audio and video communications between the wearer and an operator located at the central monitoring unit* (reads on "central station")(see at least Fig. 2B, Ele. 300a, 300b)(see at least Col. 7, lines 40-45; Col. 11, lines 15-23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers and the transdermal device of Bettinger with the video communication of Shusterman because it is "…useful to facilitate visual contact and interaction between the support staff and the patient" (Shusterman, see at least Col. 9, lines 4-9).

Claim 9:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps, Rogers and Bettinger do not specifically disclose the following limitations, but Shusterman, as shown does:

- *wherein said medication storage compartment comprises a hinged cover* (see at least Col. 28, lines 40-44).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers and the transdermal device of Bettinger with the medication storage of Shusterman because it "…saves hospital labor costs and reduces the risk of error when administering individual doses" (Shusterman, see at least Col. 18, lines 12-14).

18. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,579,231,B1 to Phipps in view of U.S. Patent 6,665,385 B2 to Rogers et al. in view of US Patent 6,539,250 B1 to Bettinger and further in view of U.S. Patent 6,796,967 B2 to Jensen.

Claim 5:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps, Rogers and Bettinger do not specifically disclose the following limitations, but Jensen, as shown does:

- *a needle compartment* (see at least Fig. 2, Ele. 134) *for housing said injection device and including an antiseptic film* (see at least Fig. 2, Ele. 150) *having a side exposed to the injection device and an opposite side exposed to a surface of a wearer's skin such that a needle included in said injection device penetrates and punctures said antiseptic film when the medication is administered* (see at least Col. 5, lines 3-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers and the transdermal device of Bettinger with the needle assembly of Jensen because it "…causes the user's skin to be sterilized and/or numbed, as the case may be, prior to penetration by the needle" (Jensen, see at least Col. 6, lines 47-50).

19. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,579,231,B1 to Phipps in view of U.S. Patent 6,665,385 B2 to Rogers et al. in view of US Patent 6,539,250 B1 to Bettinger and further in view of U.S. Patent Application Publication US 2004/0010207 A1 to Flaherty et al.

Claim 6:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps, Rogers and Bettinger do not specifically disclose the following limitations, but Flaherty, as shown does:

- *wherein said injection device* (reads on "insertion actuator") *includes a solenoid for remotely administering the medication* (reads on "drugs")(see at least Col. Lines 3-7 of Paragraph 1; lines 15-17 of Paragraph 71).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers and the transdermal device of Bettinger with the injection device of Flaherty because it provides "…a fluid infusion device for delivering medicinal fluid to the person, based on the sensing of the physiologic condition" (Flaherty, see at least the last 3 lines of Paragraph 57).

Claim 7:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps, Rogers and Bettinger do not specifically disclose the following limitations, but Flaherty, as shown does:

- *wherein said injection device includes a piezoelectric member for driving the injection device* (reads on "insertion actuator")(see at least lines 3-7 of Paragraph 1; line 17 of Paragraph 71).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers and the transdermal device of Bettinger with the injection device of Flaherty because "…other devices may be utilized for the insertion actuator and withdrawal actuator…" (Flaherty, see at least lines 15-16 of Paragraph 71).

20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,579,231 B1 to Phipps in view of U.S. Patent 6,665,385 B2 to Rogers et al. in view of US Patent 6,539,250 B1 to Bettinger, in view of US Patent 5,979,803 to Peters et al. and further in view of U.S. Patent Application Publication US 2004/0010207 A1 to Flaherty et al.

Claim 8:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps, Rogers and Bettinger do not specifically disclose the following limitations, but Brisken, as shown does:

- *wherein said injection device includes a magnetostrictive member for driving the injection device* (reads on "needle")(see at least Col. 11, lines 28-34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers and the transdermal device of Bettinger with the magnetostrictive member of Peters because it provides "…for moving needle valve element in proportion to the magnitude of the input signal to the actuator…" (Peters, see at least Col 11, lines 30-32)

Peters does not specifically disclose an injection device, but Flaherty, in at least lines 4-7 of Paragraph 1 and lines 15-16 of Paragraph 71, does.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers, the transdermal device of Bettinger and the magnetostrictive member of Peters with the injection device of Flaherty because "…other devices may be utilized for the insertion actuator and withdrawal actuator…" (Flaherty, see at least lines 15-16 of Paragraph 71).

21. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,579,231,B1 to Phipps in view of U.S. Patent 6,665,385 B2 to Rogers et al. in view of US Patent 6,539,250 B1 to Bettinger and further in view of U.S. Patent 6,564,093 B1 to Ostrow et al.

Claim 12:

The combination of Phipps/Rogers/Bettinger discloses the limitations as shown in the rejections above. Phipps, Rogers and Bettinger do not specifically disclose the following limitations, but Ostrow, as shown does:

- *Wherein said transdermal device includes a method of propelling high concentrations of a said medication* (reads on "pharmaceutical medium") or *bioactive-agent transdermally* (see at least Col. 3, lines 24-28; Col. 14, lines 17-21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the transceiver of the central monitoring unit of Rogers and the transdermal device of Bettinger with the transdermal device of Ostrow because it provides "…unencumbered self-powered transdermal patch system for drug delivery that would deliver large-molecule drugs in an efficient manner to the affected site…" (Ostrow, see at least Col. 2, lines 49-55).

22. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,579,231,B1 to Phipps in view of U.S. Patent 5,204,670 to Stinton in view of US Patent 6,409,663 B1 to Mercereau and further in view of U.S. Patent 5,957,895 to Sage et al.

Claim 13:

Phipps discloses the following limitations:

- *collecting data during normal activities and when a wearer is not experiencing a serious medical condition* (reads on "continuous real time collection")(see at least Col. 3, lines 9-12);

- *collecting and comparing* (reads on "evaluate") *real time data with said base-line data (*see at least Col.1, lines 9-13; Claim 32, lines 1-7);

- *recognizing the existence* of *a medical condition when said real time data exceeds an acceptable threshold* (see at least Col.2, lines 60-62; Col. 7, lines 42-45);

Phipps does not disclose the following limitations, but Stinton, as shown does:

A biometric system to unequivocally recognize the wearer (see at least Col. 21, line 68 through Col. 22, line 2);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps with the biometric system of Stinton because it provides "…a flexible monitoring system that measures the compliance or non-compliance of a monitored individual against a prescribed performance or behavior standard" (Stinton, see at least Col. 6, 23-26).

Phipps and Stinton do not specifically disclose the following limitations, but Mercereau, as shown does:

- *storing said data as base-line data* (see at least Col. 6, lines 66 – Col. 7, line 3);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps and the biometric system of Stinton with the base-line data of Mercereau because it provides "…can be used to detect, correct and/or prevent unhealthy or sub-optimal conditions and to direct growth toward health or optimal conditions" (Mercereau, see at least Col. 4, lines 25-28).

Phipps, Stinton and Marcereau do not specifically disclose the following limitations, but Sage, as shown does:

- *administering an injection of medication when said medical condition is recognized* (see at least Col. 1, lines 9-10)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the biometric system of Stinton and the base-line data of Mercereau with the injection device of Sage because it provides "…an automatic injection device which is capable of infusing a drug solution or other liquid therapeutic preparation into the skin of a patient…" (Sage, see at least Col. 2, lines 14-17).

Claim 14:

The combination of Phipps/Stinton/Marcereau/Sage discloses the limitations as shown in the rejections above. Phipps further discloses the following limitations:

- *confirming consciousness* (reads on "vital signs stop") *with said wearer to determine whether an injection should be automatically administered* (see at least Col. 2, lines 45-49; Col. 5, lines 12-18).

Phipps does not specifically disclose that an injection is administered, but Sage, in at least Col. 1, lines 9-10, does.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the biometric system of Stinton and the base-line data of Mercereau with the injection device of Sage because it provides "...an automatic injection device which is capable of infusing a drug solution or other liquid therapeutic preparation into the skin of a patient..." (Sage, see at least Col. 2, lines 14-17).

Claim 15:

The combination of Phipps/Stinton/Marcereau/Sage discloses the limitations as shown in the rejections above. Phipps further discloses the following limitations:

- *providing a list of medical instructions to said wearer* (see at least Col. 5, lines 30-35).

Claim 16:

The combination of Phipps/Stinton/Marcereau/Sage discloses the limitations as shown in the rejections above. Phipps further discloses the following limitations:

- *alerting medical authorities* (reads on "call to 911") *when a medical condition* (reads on "adverse conditions") *has been determined* (see at least Col. 2, lines 41-45; lines 49-54).

Claim 17:

The combination of Phipps/Stinton/Marcereau/Sage discloses the limitations as shown in the rejections above. Phipps, Marcereau and Sage do not specifically disclose the following limitations, but Stinton, as shown does:

- *biometric system for recognizing and identifying the wearer based upon (1) one or more intrinsic physical or behavioral traits* (see at least Col. 21, line 68 through Col. 22, line 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the personal medical monitoring system of Phipps, the base-line data of Mercereau and the injection device of Sage with the biometric system of Stinton because it provides "...a flexible monitoring system that measures the compliance or non-compliance of a monitored individual against a prescribed performance or behavior standard" (Stinton, see at least Col. 6, 23-26).

Conclusion

23. Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **JOY CHNG** whose telephone number is **571.270.7897**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES A. REAGAN** can be reached at **571.272.6710**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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or faxed to **571-273-8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

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/JOY CHNG/

15 January 2009

Examiner

Art Unit 4114

/Naeem Haq/

Supervisory Patent Examiner, Art Unit 4117